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09/701,989	01/29/2001	Alexandros Makriyannis	UCON/150/PC/	1360

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ALIX YALE & RISTAS LLP  
750 MAIN STREET  
SUITE 1400  
HARTFORD, CT 06103

EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/701,989

Applicant(s)

MAKRIYANNIS ET AL.

Examiner

Clinton Ostrup

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

Claims 1-14 are pending in this application.

### ***Priority***

Priority to US Provisional Application Number 60/088,568 filed June 9, 1998 and PCT/US99/12900, filed June 9, 1999 has been acknowledged.

### ***Election/Restrictions***

Applicant's election with traverse of claims 1-7 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that The MPEP Appendix A1, Annex B, subsection c is concerned with unity of invention between an independent claim and claims dependent therefrom if the independent claim does not avoid the prior art, but the instant lack of unity requirement is between two independent claims. Applicants go on to argue that independent claim 1 is drawn to a method of inhibiting transport of anandamide and 8 is drawn to a compound sharing virtually X, Y, and virtually all the Z moieties with the compound used in the method of claim 1.

The examiner agrees that claims 1 and 8 share similar compounds and this is the technical feature unifying the claims. However, the compounds are not novel, therefore there is no "**special technical feature**" unifying the inventions. Therefore, the question of unity has been reconsidered, *a posteriori*.

In response to applicants argument that the claims are independent and are therefore not subject to the unity of invention requirement of Appendix A1, Annex B, subsection c, this argument is not found convincing because subsection c clearly

Art Unit: 1614

states "Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims."

Applicants argument that MPEP Appendix A1, Annex b, subsection e allows for combinations of different categories of claims is not convincing because although the examiner agrees that different categories of claims must be examined together, this is only relevant when there is a "Special technical feature" unifying the claims. Since the examiner has cited prior art, which clearly shows the compounds as claimed are not novel, this argument is not found persuasive.

In response to applicants argument against the election of species, it should be remembered that the purpose of an election of species requirement is to simplify the search and issues considered during prosecution, and that because this is so, the ultimate allowance of a generic claim will encompass all additional species within the scope of the allowed genus. Stated alternatively, the purpose of an election of species requirement, as opposed to a restriction between claim groups, is to reduce the burden on the examiner during prosecution only; a full search is merely postponed until allowance of the generic claim. Furthermore, MPEP Appendix A1, Annex B subsection f(v) clearly states that "when dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised." In the instant case, the examiner reconsidered the unity of invention and determined that a lack of unity exists.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 8-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

The requirement is still deemed proper and is therefore made FINAL.

***New Matter Objection***

The amendment filed July 31, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants amendment to claim 8, "wherein Z cannot be hydrogen if Y is C(O)-NH-" is not supported in the disclosure as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

**New Matter Rejection - 35 U.S.C. 112, First Paragraph**

Although claims 8-14 have been withdrawn from consideration as being drawn to a non-elected invention, they are hereby being rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

Art Unit: 1614

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention in the interest of compact prosecution. Applicants amendment to claim 8, "wherein Z cannot be hydrogen if Y is C(O)-NH-" is not supported in the disclosure as originally filed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 12-19 of copending Application No. 09/328,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compounds and methods of inhibiting the transport of anandamide in an individual or animal by administration of said compounds to said individual or animal. The compounds and methods of administering said compounds overlap one another in the conflicting claims and/or are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Calignano et al., Potentiation of Anandamide Hypotension by the Transport Inhibitor, AM404, European Journal of Pharmacology, Oct 15, 1997, 337 (1) R1-2. See: abstract.

Calignano et al teach AM404 as an inhibitor or carrier-mediated anandamide transport. AM404, meets the compound of instant claims 1, 3, and 5-7 when X is has a terminal radical of a hydrogen, Y is a carbonyl amine radical, and Z is a hydroxy substituted aryl group.

Claims 1, 3, and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Beltramo et al., Functional Role of High-Affinity Anandamide Transport, as Revealed by Selective Inhibition, Science, August 22, 1997, 227 (5329) 1094-7.

Beltramo et al teach AM404 as inhibiting high affinity anandamide accumulation in rat neurons and astrocytes *in vitro* and indicated that this accumulation resulted from carrier-mediated transport. The authors teach that AM404 does not activate cannabinoid receptors or inhibit anandamide hydrolysis, but it functions as an enhancer of receptor-mediated anandamide responses *in vitro* and *in vivo*. See: page 1096, col,2-3.

AM404, meets the compound of instant claims 1, 3, and 5-7 when X is has a terminal radical of a hydrogen, Y is a carbonyl amine radical, and Z is a hydroxy substituted aryl group.

### ***Conclusion***

Note: A method of inhibiting transport of anandamide in an individual or animal comprising administering to the individual or animal, in need thereof, a therapeutically effective amount of the elected compound on page 5, lines 6-7, in Paper No. 9, filed January 21, 2003, appears to be allowable over the prior art and a claim drawn to said method will be considered favorably.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Khanolkar et al., Head Group Analogs of Arachidonylethanolamide, the Endogenous Cannabinoid Ligand, J. Med. Chem. 1996,



Art Unit: 1614

39, 4515-4519, shows the anandamide analogs, and their respective affinities for the brain cannabinoid receptor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup  
Examiner  
Art Unit 1614



Frederick Krass  
Primary Examiner  
Art Unit 1614



April 7, 2003